

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-50394D85-E261-479B-90D3-E805CF22C1A5_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M36460_02_01
 DOI Ref: 61d8y

© 2025 USPC
 Do not distribute

Haloperidol Tablets

DEFINITION

Haloperidol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2021)

ASSAY

Change to read:

• PROCEDURE

▲**Buffer:** Dissolve 6.8 g of [monobasic potassium phosphate](#) in 1 L of [water](#).▲ (USP 1-May-2021)

Mobile phase: [Methanol](#) and ▲**Buffer**▲ (USP 1-May-2021) (60:40). Adjust with 1 N [sodium hydroxide](#) or [phosphoric acid](#) to a pH of 4.0.

Standard solution: 0.1 mg/mL of [USP Haloperidol RS](#) in *Mobile phase*

Sample solution: Nominally 0.1 mg/mL of haloperidol ▲from Tablets▲ (USP 1-May-2021) prepared as follows. Transfer an equivalent of about 10 mg of haloperidol from finely powdered Tablets (NLT 20) to a 100-mL volumetric flask. Add 60 mL of *Mobile phase*, sonicate ▲with occasional shaking for 30 min. Dilute with *Mobile phase* to volume. Pass the solution through a filter of suitable pore size, discarding the first 1 mL of the filtrate.▲ (USP 1-May-2021)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2021)

Column: ▲4.6-mm × 25-cm; 5-μm▲ (USP 1-May-2021) packing [L1](#)

▲**Column temperature:** 30°▲ (USP 1-May-2021)

Flow rate: 1 mL/min

Injection volume: 15 μL

▲**Run time:** NLT 2 times the retention time of haloperidol▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT ▲1.0%▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of the *Sample solution*

r_s = peak response of the *Standard solution*

C_s = concentration of [USP Haloperidol RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of haloperidol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#).

Medium: [Simulated gastric fluid TS](#) without enzyme; 900 mL

Apparatus 1: 100 rpm

Time: 60 min

▲ **Buffer** and ▲ (USP 1-May-2021) **Mobile phase:** Prepare as directed in the Assay.

Standard solution: A known concentration of [USP Haloperidol RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution*.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: ▲ 4.6-mm × 25-cm; 5-μm ▲ (USP 1-May-2021) packing [L1](#)

▲ **Column temperature:** 30° ▲ (USP 1-May-2021)

Flow rate: 1 mL/min

Injection volume: 50 μL

▲ **Run time:** NLT 2 times the retention time of haloperidol ▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT ▲ 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s/L) \times V \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Haloperidol RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium* (900 mL) ▲ (USP 1-May-2021)

Tolerances: NLT 80% (Q) of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$) is dissolved.

Change to read:

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

▲ (USP 1-May-2021)

IMPURITIES

Add the following:

▲ • **ORGANIC IMPURITIES**